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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1657	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,507	PARISSENTI ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

General Informal Matters

1. Note that the correct Serial Number of the instant Non-Provisional Application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/580,507. Please ensure that the correct U.S. Serial Number (i.e., 10/580,507) for the instant application is cited in all future correspondence with this Office.

2. The assigned Art Unit location for the instant application (i.e., 10/580,507) at the USPTO is 1657. To aid in correlating any papers for the instant application (i.e., 10/580,507), all further correspondence regarding for the instant application (i.e., 10/580,507) should be directed to Art Unit 1657.

3. The assigned Examiner for the instant application (i.e., 10/580,507) under prosecution at the USPTO is Dr. Kailash C. Srivastava. To aid in correlating any papers for the instant application (i.e., 10/580,507), all further correspondence regarding the instant application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

4. Claims 1- 18 are currently pending.

Election /Restriction

5. This application contains the following groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

- Group Ia, consisting of claims 1-5 and 15-17, drawn to a method to determine a sequence to administer multiple chemotherapeutics to kill cancerous cells to reduce drug-resistance induction in a patient;

  Group Ib consisting of Claims 12-14 drawn to a composition comprising a plurality of isogenic cell lines obtained from a single cancerous tumor.

- Group II, consisting of claim 6, drawn to a method to prepare a medicament comprising caspase-9, or procaspase-9 to enhance the effectiveness of an anthracycline anticancer drug in a patient resistant to anthracycline medication.

- Group III, consisting of claim 7, drawn to a method to determine resistance of cancerous cells to killing by an anthracycline drug because of reduced caspase-9, or procaspase-9 production.

- Group IV, consisting of claims 8-11, drawn to a method to screen drug candidates to select a lead anticancer drug among a plurality of candidate drugs, the criterion of selection being reduced capacity to induce cross resistance to said drug in a patient.

- Group V consisting of Claim 18 drawn to a composition comprising a complete panel of isogenic drug-resistant MCF-7 breast tumor cell lines.

Inventions are Independent or Distinct

6. The inventions listed as Groups I-V, despite being related to cancer cell or a cancerous tumor in a patient do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of each one of the inventive groups described *supra* is as follows:

- invention in group I despite comprising the isogenic cell line component is to identify an order in which drugs should be administered to overcome cross-resistance to specific group of cancer-treating drugs in a patient;

- Group II invention is specific to a medicament preparation process, wherein the technical feature resides in caspase-9 and/ or procaspase-9 that would impart the functionality of enhancing the effectiveness of a certain group of anti-cancer drug;

- In Group III invention, the special distinguishing technical feature is the assessment of the concentration/amount of caspase-9 or procaspase-9 in a cancerous cell;

- The special technical feature of Group IV invention is a screening assay for an anti cancer drug without taking in to consideration any enhancement factors or comparative effectiveness of said drug with an anthracycline drug.

- Group V invention is drawn to a specific cancerous cell that would be applicable for a variety of evaluations that may or may not involve determining effectiveness of a novel anti-cancer drug or of a particular physiological, or pharmacokinetic study or may be applicable for of all of above.

Thus, none of the inventions in Groups I-V share the same or similar technical feature/ characteristics of invention in one of the other inventive groups. Since no special technical feature exists among the inventions in groups I-III, there is no unity of invention.

7. Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above, and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

a. the inventions have acquired a separate status in the art in view of their different classification;
b. the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
c. the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
d. the prior art applicable to one invention would not likely be applicable to another invention;
e. the inventions are likely to raise different non-prior art issues under 35 U.S.C. §101 and/or 35 U.S.C. §112, first paragraph.

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 C.F.R. §1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 C.F.R. §1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of

the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Species Election

8. This application contains Claims directed to the following patentably distinct non-taxonomic species:

A. cells originating from either breast cancer, or uterine cancer as listed in Claims 4, 11 and 13;

B. forms of a single candidate drugs selected from the group consisting of structural isomers, positional isomers, polymorphic forms, chemical analogs, salts and tautomers as listed in Claim 10;

C. three different panels of isogenic cells as listed in Claim 12;

9. The non-taxonomic species listed *supra* are independent or distinct because claims to the different non-taxonomic species recite the mutually exclusive characteristics of such non-taxonomic species. In addition, these non-taxonomic species are not obvious variants of each other based on the current record.

Accordingly, the search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because the inventive groups discussed above incorporate numerous components and numerous ingredients within each of the same, single invention. For example, to conduct a literature search for invention in Group I that is constituted of different components/steps as outlined above, one would be searching for a total number of combinations that may be a factorial of at least 11 components encompassing all the components with each one of the components/ingredients up to ingredient number 1 (i.e. 11*10, 11*9, 11*8, 11*7, 11*6, 11*5, -----11*1). When one adds additional limitations (e.g., different drugs) to the claimed 12 components listed above, the number of combinations multiplies by geometric levels. Thus, this group alone will exert an enormous search burden on the Examiner. Therefore, if the applicants elect inventions of Groups I-II above, applicants must also make election of species as appropriate by electing **only one species** as noted below and as appropriate):

i. For inventions in Groups I-V, **only one species** of cancerous cells, either breast , or uterine as listed in sub-tem A of item 8 *supra*;

ii. For invention in Group I additionally, only one of the isogenic cell line population

amongst those listed in sub-item C (i.e., Claim 12) of item 8 *supra*; and

iii. For invention in Group IV, additionally only one form of the candidate drugs amongst those listed in sub-item B (i.e., Claim 10) of item 8 *supra.*

10. Applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merit to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently Claims 1, 6-8, 12, 15 and 18 are generic claims.

There is an examination and search burden for the above-mentioned patentably distinct non-taxonomic species due to their mutually exclusive characteristics. The non-taxonomic species require a special field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely raise different non-prior art issues under 35 U.S.C. §101 and or 35 U.S.C. §112, first paragraph.

11. **Applicants are advised that the reply to this requirement to be complete must include (I) an election of a species to be examined** among the species listed in categories i-iii even though the requirement may be traversed (37 C.F.R. §1.143) **and (II) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable, or that all claims are generic is considered non-responsive unless accompanied by an election.

12. The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 C.F.R. §1.144. If claims are added after the election, applicant(s) must indicate which of these claims are readable on the elected species.

Should applicant(s) traverse on the ground that the species are not patentably distinct, applicant(s) should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other species. Upon the allowance of a generic claim, applicants will be entitled to

consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141.

13. In accordance with 37 C.F.R. §1.499, Applicants are required that a reply to this requirement must include an identification of the species that are listed in categories i-iii and is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of a Group and a corresponding species. If claims are added after the election, applicant must indicate which Claims are readable upon the elected species [M.P.E.P. §809.02(a)].

14. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(I).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

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19 June 2008
/David M. Naff/
Primary Examiner, Art Unit 1657